America's Blood Centers

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Reference: Docket No. 98N-0673: Final Rule: Revisions to the Requirements Applicable& Blood, Blood Components and Source Plasma

To Whom it May Concern:

America's Blood Centers appreciates the opportunity to comment on the Center for Biologics Evaluation and Research's recent direct final rule removing, revising or updating certain blood and plasma regulations. With certain exceptions detailed below, in general, we find the revisions helpful and noncontroversial.

We have the following comments on specific aspects of the final rule:

Section 640.23(a). The rationale for considering ABO/Rh testing of plateletpheresis donors valid only for three months is not clear. Since donors do not change their blood types, the only reason ever to redetermine the blood type is to confirm that the samples were obtained from the correct donor. If it is not important to do this at each donation, then it is equally unimportant to ever repeat it. It would make more sense to state that further typing need not be done once two identical typings were on record. We also question why plateletpheresis donors are singled out for this exception.

Sections 640.3(c)(1) and 640.63(c)(11). We request that FDA clarify the revisions in this section related to hepatitis deferrals "after the age of 11" to specify whether this means after the 11th birthday or after the 12th birthday (i.e. when one is' no longer 11).

Section 640.34(b) (c) and (d). In these sections, FDA has changed the time period for preparation of components (FFP, Platelets, Cryoprecipated AHF) from "4 hours" to "within the time period specified for the direction for use for the specific device." To our knowledge, few if any manufacturers include the time period for preparing FFP or cryo in their labeling. Instead, they refer to the previous regulations under Section 640.34 as well as the American Association of Blood Banks' *Standards.*

We would appreciate guidance in this area from FDA or the manufacturers.

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Section 640.34 (b). We request that FDA delete the change in this section that specifies that plasma for Fresh Frozen Plasma must be "frozen solid" within the timeframe specified by the device and replace it with "separated and placed in a freezer at -18 or colder within 8 hours of collection," as specified by the American Association of Blood Banks in its *Standards.*

We are unaware of any definition in the regulations for "frozen solid." Moreover, the term could be interpreted as requiring the unit to reach the glass transition phase for a liquid. This would be a temperature of less than minus 120 degree C. This would be highly unrealistic, since the plastic containers would shatter at these temperatures.

640.4(g)(2) We request that the final rule make allowance for collection of the samples for laboratory testing within 24 hours of the collection of the component in certain circumstances.

This is particular important for the collection of granulocytes since, for reasons of cell viability, granulocytes must be transfused as soon as possible after collection. If the sample for testing is drawn at the beginning of the collection, cell integrity would be severely compromised if transfusion were delayed for completion of testing (12-24 hours).

640.61. We request that the rule be modified to specify that informed consent for donors of Source Plasma, Plasma and Platelets may be provided by responsible personnel under the guidance of a blood establishment physician.

The requirement that informed consent for such donors be delivered personally by a physician, is unnecessary, unreasonable, and unworkable. There is no reason to single out these types of collections for this requirement. These collections are accomplished in many blood centers at satellite and mobile collection sites, and physicians are not routinely present at these sites.

Section 640.62. We request reconsideration of the requirement that a qualified licensed physician be available to attend to the donor within 15 minutes when a pheresis procedure is being performed-in light of much safer automated collection equipment and much more successful and ubiquitous EMS services in communities since the 1988 plateletpheresis guidelines were issued. If this requirement must be retained, it should permit such collections if a physician or an emergency response team is available within the fifteen minute period.

Adverse effects experienced during apheresis donation are less frequent than for whole blood donation and are very unusual. A number of larger blood centers with decentralized apheresis operations have procedures that call for activation of the local EMS system in the event of serious donor reaction. ABC believes this actually is a far better safeguard for the donors than having a physician drive to the site to evaluate the reaction. If the reaction is serious enough to require a physician, the donor would be better served by being transported immediately to an emergency room without having to wait up to 15 minutes for a physician to appear. In addition, cardiovascular and other emergencies are much better handled by experienced emergency response teams than by blood establishment physicians or contract pathologists.

Once again, thank you for the opportunity to comment. If you would like to discuss the above questions further, I can be reached at (302) 737-8405 extension 767.

Yours truly,

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